

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bulk Manufacturer of Controlled Substances Application: IRIX Manufacturing, Inc.

[Docket No. DEA-392]

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before [INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated his authority under the Controlled Substances

Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR

0.100(b). Authority to exercise all necessary functions with respect to the promulgation
and implementation of 21 CFR part 1301, incident to the registration of manufacturers,
distributors, and dispensers of controlled substances (other than final orders in connection
with suspension, denial, or revocation of registration) has been redelegated to the Deputy

Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant

Administrator") pursuant to section 7 of 28 CFR pt. 0, subpt. R, App.

In accordance with 21 CFR 1301.33(a), this is notice that on August 14, 2014, IRIX

Manufacturing, Inc., 309 Delaware Street, Building 1106, Greenville, South Carolina

29605, applied to be registered as a bulk manufacturer of noroxymorphone (9668), a

basic class of controlled substance listed in schedule II.

The company plans to manufacture the listed controlled substance as API for clinical

trials.

Dated: January 9, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

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